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Nawal Hijjawi

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EXAMINER

AFREMOVA, VERA

ART UNIT

PAPER NUMBER

1657

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DELIVERY MODE

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



### **DETAILED ACTION**

Claims 1-40 (preliminary amendment 8/25/2006) are pending and subject to restriction requirement.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 7-12 and 14, drawn to a first method of using a first cell free medium product for culturing *Cryptosporidium* to a second lifecycle stage.

Group II, claim(s) 5, drawn to a second method of using a first cell free medium product for culturing *Cryptosporidium* to complete its lifecycle.

Group III, claim(s) 6, drawn to a third method of using a first cell free medium product for culturing *Cryptosporidium* to increase biomass.

Group IV, claim(s) 13, drawn to a fourth method of using a first cell free medium product for culturing *Cryptosporidium* to harvest oocytes.

Group V, claim(s) 15-20, drawn to a first product that is a cell free culture medium comprising buffer, inorganic salts, amino acids, vitamins, etc.

Group VI, claim(s) 21-23, drawn to a fifth method of using a first cell free medium product for preparing an immunogenic preparation with *Cryptosporidium* antigen.

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Group VII, claim(s) 24-29, drawn to a second product that is a therapeutic composition with effective amount of *Cryptosporidium*.

Group VIII, claim(s) 30, drawn to a first method of using a second product such as a therapeutic composition with effective amount of *Cryptosporidium* for treating *Cryptosporidium* infection.

Group IX, claim(s) 31 and 34-40, drawn to a first method for detecting *Cryptosporidium* in a sample.

Group X, claim(s) 32 drawn to a second method for detecting *Cryptosporidium* in a sample.

Group XI, claim(s) 33, drawn to a third method for detecting *Cryptosporidium* in a sample.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

This application contains claims drawn to more than one of permissible combinations of categories of inventions such as more than one product(s) and more than one process of use said products. Furthermore, a “special technical feature” (that defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art) is known in the prior art. For example: a first product as claimed such as that is a cell free culture medium comprising buffer, inorganic salts, amino acids, vitamins, etc. is a common chemically defined cell culture medium including DMEM, Hams’ or RPMI. Further, a second product as claimed a therapeutic composition with effective amount of *Cryptosporidium* is also known in the prior art, for

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example: US 2003/0235903 (Thompson et al) teaches a vaccine composition with effective amount of *Cryptosporidium* as intended for immunizing animals against *Cryptosporidium* infection. Thus, unity of inventions is lacking. See MPEP 1850. 37 CFR 1.475.

37 CFR 1.475. Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ( "requirement of unity of invention "). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features " shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and a process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

March 2, 2010

/Vera Afremova/

Primary Examiner, Art Unit 1657